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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,416	09/25/2003	Robert Mills	46527	5060

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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,416	MILLS ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *4-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on February 15, 2006.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

This application contains claims 4-9 drawn to an invention nonelected without traverse in the reply filed on December 1, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-3 are under examination.

Claim Rejections - 35 USC § 112

Claims 1-3 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "wherein the extract comprises 1.5 mg of berberine alkaloid per ml of extract" in Claim 1. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on February 15, 2006 now recite a "A skin treatment composition comprising an extract of *Mahonia aquifolium* in a liposome delivery system, wherein the extract comprises 1.5 mg of berberine alkaloid per ml of extract". However, the specification as originally filed provides only for an extraction process that "yields a finished *Mahonia aquifolium* extract with a

concentration of approximately 1.5mg/ml berberine alkaloid", as set forth on page 5, lines 23-25, of the present specification.

Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concepts for a composition comprising an extract of *Mahonia aquifolium* in a liposome delivery system, wherein the extract comprises 1.5 mg of berberine alkaloid per ml of extract, with regard to Claim 1. There is only one exemplified composition comprising a concentration of **approximately** 1.5mg/ml berberine alkaloid. For instance, nowhere in the specification as originally filed does Applicant expressly disclose a skin treatment comprising the claim-designated plant extract in a liposome delivery system, wherein the extract comprises 1.5 mg of berberine alkaloid per ml of extract. While Applicant does an extraction process that "yields a finished *Mahonia aquifolium* extract with a concentration of approximately 1.5mg/ml berberine alkaloid, and; while Applicant does that "The product obtained from this extraction process is then utilized to prepare a pharmaceutical composition", such as "by combining the *Mahonia aquifolium* extract in a liposome delivery system", please note that disclosing a process to obtain an extract comprising a particular component (berberine alkaloid) with a concentration amount of **approximately** of the plant extract does not necessarily translate into an extract comprising the claim-designated amount of (berberine alkaloid) the particular component since "**approximately** 1.5mg/ml berberine alkaloid" does not necessarily

encompass the claim-designated amount of "**approximately** 1.5mg/ml berberine alkaloid". For example, "**approximately** 1.5mg/ml berberine alkaloid" could encompass concentrations less than "1.5mg/ml berberine alkaloid" but not necessarily "1.5mg/ml berberine alkaloid", as presently claimed by Applicant. This is not sufficient support for the new aforementioned genera/genus. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Newly applied as necessitated by amendment.

Claims 1-3 either recite, or depend upon a claim which recites 'A skin treatment composition comprising an extract of *Mahonia aquifolium* in a liposome delivery system, wherein the extract comprises 1.5 mg of berberine alkaloid per ml of extract'. It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of extracts.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* extracts. The possible variations of extracts are limitless. Although Applicant has disclosed a process for obtaining an extract of *Mahonia aquifolium* using several solvents (for example, water and alcohol (type unspecified) from bark and twigs of the plant which could potentially be used to extract *Mahonia aquifolium* (page 4, line 7 to page 8, line 23 of the instant specification) this disclosure is actually a *very few* number in comparison to the enormous, *potentially thousands* of types of extracts which could be obtained from *Mahonia aquifoliu*m. The reason for this large amount of permutations is because extraction techniques are often coupled in order to obtain a product; for example:

1) a water extraction followed by an alcoholic extraction: the product obtained is an extract.

2) a supercritical extraction (CO_2) followed by an alcoholic and then a non-polar solvent extraction (e.g., chloroform): the product is an extract.

3) a benzene extraction followed by a water extraction and chromatographic separation: the product is an extract.

4) a water/chloroform extraction (e.g., in a separatory funnel), followed by collection of the water layer, chromatographic separation and crystallization of an isolate: the product is an extract.

5) squeezing the plant to obtain a juice: the product is an extract.

6) dipping the plant in an organic solvent to remove the waxy layer: the product is an extract.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F. 2d

1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F. 3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398. The specification lacks sufficient variety of species of extracts to reflect this variance in the genus since the specification does not provide sufficient examples of such a genus of extracts.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of 'extract' and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention and thus, this rejection is proper.

Claim 1, as amended, and Claims 2-3 is/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth in the previous Office action.

Claims 1-3 are rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art). For example, is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the step(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these

critical limitations as set forth above, the claims do not adequately define the instant invention.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
May 1, 2006